Common Data Element Development for the Division of Cancer Protection (DCP) and the Center for Cancer Research (CCR)

July 19, 2004
Tommie Curtis
SAIC, Contractor for NCICB

DCP and CCR – CDE Development

- ➢ Created from Case Report Forms (CRFs)

- ➢ Developed by NCI committees/protocols

- ➢ Used in Oracle Clinical (C3D) and program specific applications

The Life of a Common Data Element

➢Determine the information to be collected (the questions, permissible values, standard code sets)

➢Plan the data analysis to support study objectives

➢Identify reporting requirements

➢Collect application system requirements

➢Design CRFs

➢Develop data elements and register in the caDSR – reuse of CDEs is a basic assumption

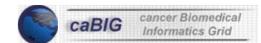➢Obtain CDEs from caDSR for applications or eforms – use the caBIO API

An Example

<DCP Protocol Number>

BASELINE MEDICAL/SURGICAL HISTORY

ORGANIZATION (CODE)	PARTICIPANT ID	VISIT TYPE	VISIT DATE (MM/DD/YYYY)
_____	_____	_____	__ __ / __ __ / __ __ __ __

Body System	Normal	Abnormal	Comments (Required if Abnormal)
H/E/E/N/T	☐	☐	
Neck	☐	☐	
Respiratory	☐	☐	
Cardiovascular	☐	☐	
Gastrointestinal	☐	☐	
Musculoskeletal	☐	☐	
Dermatologic	☐	☐	
Hematologic/Lymph	☐	☐	
Endocrine/Metabolic	☐	☐	
Genitourinary	☐	☐	

Sample CDEs

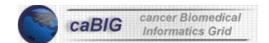|	A	B	C	D	E	F
1	**Long Name**	**Preferred Definition**	**Max Length**	**Format**	**Workflow Status**	**Registration Status**
2	Organization Name	The formal name of an organization.	100		Released	Qualified
3	Organization Code	The code that represents an organization.	10		Released	Qualified
4	Participant Identifier	The identifier assigned to a study participant.	10		Released	Qualified
5	Visit Date	The date of a participant contact.	8	MM/DD/YYYY	Released	Qualified
6	Visit Type Text	The text that describes a participant contact.	80		Released	Qualified
7	Body System Type	An anatomic structure that consists of all members of one or more organ subclasses; these members are interconnected by anatomical structures or body substances.	64		Released	Qualified
42	Body systems Normal, Abnormal, Not Examined Indicator	The indicator that respresents whether the system is normal, abnormal or not examined.	12		Released	Qualified
46	Abnormal Comment Text	The text that describes the abnormal medical/surgical events during the participants lifetime.	200		Released	Qualified

A Bit More Complicated Example

<DCP Protocol Number>

PHYSICAL EXAM

ORGANIZATION (CODE)	PARTICIPANT ID	VISIT TYPE	VISIT DATE (MM/DD/YYYY)
_____	_____	_____	__ __ / __ __ / __ __ __ __

Examination Date (MM/DD/YYYY): __ __ / __ __ / __ __ __ __

Height: __ __ __.__ __	☐ cm ☐ in	Weight: __ __ __.__ __	☐ kg ☐ lb	Temperature: __ __ __.__ __	☐ °C ☐ °F
☐ Not Obtained		☐ Not Obtained		☐ Not Obtained	

Pulse Rate: __ __ __	Respiration Rate: __ __ __	Blood Pressure: __ __ __ / __ __ __
☐ Not Obtained	☐ Not Obtained	☐ Not Obtained Systolic (mm Hg) Diastolic (mm Hg)

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CSAERS Application

▸ Supports reporting Severe Adverse Events (SAE)

▸ Requirements based on current paper reporting forms – committee created a master set of SAE information

▸ Created CDEs and permitted values (including using appropriate data standards) for the master set of information

▸ Registered CDE in caDSR (119 master CDEs)

▸ Obtained CDEs (99 for the application) via caBIO API to develop application. Used the 'question' as the eform label. Used Value Meanings for the descriptive help text for permissible values.

Workflow Status

http://ncicb.nci.nih.gov/NCICB/core/caDSR/ConsensusWorkflowStatus.xls

	A	C	D	E	F	G	H	I
1	Status	Are Version Rules mandatory?	Can Draft Mod version be created?	Can be designated?	Current/Planned Use			
2					CCR	CTEP	DCP	SPOREs
3	Draft New	no	no	no	yes	yes	yes	yes
4	Draft Mod	yes	yes	yes	yes	yes	yes	yes
5	Approved for Trial Use	yes	yes	yes	no	yes	yes	no
6	Committee Submitted	no	no	no	no	yes	no	no
7	Committee Submitted Used	yes	yes	yes	no	yes	no	no
8	Committee Approved	yes	yes	yes	no	yes	no	no
9	Released	yes	yes	yes	yes	yes	yes	yes
10	Retired Withdrawn	yes	no	no	yes	yes	no	yes
11	Retired Phased Out	yes	no	no	yes	yes	yes	yes
12	Retired Archived	yes	no	no	no	yes	no	no
13	Retired Deleted	yes	no	no	yes	yes	yes	yes
14	Released-non-compliant	yes	yes	yes	current only	current only	current only	current only

Questions?

- **caDSR Home Page**
  - http://ncicb.nci.nih.gov/core/caDSR

- **CDE Browser**
  - http://ncicb.nci.nih.gov/cdebrowse/

- **CDE Curation Tool**
  - http://ncicb.nci.nih.gov/cdecurate/

- **Administration Tool**
  - http://cadsr-prod.nci.nih.gov/

- **CCRR**
  - http://ccrr-prod.nci.nih.gov/ccrr/

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